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Artificial intelligence medical device - Quality requirements and evaluation - Part 1: Terminology

人工智能医疗器械　质量要求和评价　第 1 部分：术语

(English translation)

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Foreword

ChinaStandards.net is in charge of this English translation. In case of any doubt about the English translation, the Chinese original shall be considered authoritative.

This document is developed in accordance with the rules given in GB/T 1.1-2020 *Directives for standardization - Part 1: Rules for the structure and drafting of standardizing documents*.

This document is Part 1 of YY/T 1833 under the general title of *Artificial intelligence medical device - Quality requirements and evaluation*. The following parts of YY/T 1833 have been issued:

——*Part 1: Terminology*;

——*Part 2: General requirements for datasets*.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing body of this document shall not be held responsible for identifying any or all such patent rights.

This document was proposed by the National Medical Products Administration of People's Republic of China.

This document is under the jurisdiction of the Technical Organization on AI Medical Device of Standardization Administration of China.

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Introduction

In recent years, artificial intelligence medical devices have continued to develop and become an emerging trend in the field of medical device standardization. China has initially established a standard system for artificial intelligence medical devices. In the standard system, YY/T 1833 *Artificial intelligence medical device - Quality requirements and evaluation* is the basic general standard to provide guidance for standardization activities in the subdivision field, which is to be composed of eight parts.

——*Part 1: Terminology*, designed to provide terminology for the quality evaluation activities of artificial intelligence medical devices.

——*Part 2: General requirements for datasets*. designed to propose the general quality requirements and evaluation methods for datasets.

——*Part 3: General requirement for data annotation*, designed to propose the quality requirements and evaluation methods for data annotation.

——*Part 4: General requirements for traceability*, designed to propose the general requirements and evaluation methods for traceability of artificial intelligence medical devices.

——*Part 5: Security requirements for algorithm*, designed to standardize the security requirements and evaluation methods for artificial intelligence algorithms used for artificial intelligence medical devices.

——*Part 6: Environment requirements*, designed to standardize the requirements and evaluation methods for operating environmental condition of artificial intelligence medical devices.

——*Part 7: Privacy protection requirements*, designed to enhance the ability of artificial intelligence medical devices to protect receivers' privacy.

——*Part 8: Ethical requirements*, designed to realize the requirements of artificial intelligence ethics from the technical level and protect people's rights and interests.

This document provides basic and common terminology for other parts. For other parts, special terminology in specific contexts may be supplemented as needed during the drafting.

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Artificial intelligence medical device - Quality requirements and evaluation - Part 1: Terminology

1 Scope

This document defines the terms and definitions used for the quality requirements and evaluation of artificial intelligence medical devices.

This document is applicable to artificial intelligence medical devices.

2 Normative references

No normative reference is listed in this document.

3 Terms and definitions

3.1 Basic technical terms

3.1.1
artificial intelligence; AI
ability of functional units that exhibit various functions related to human intelligence (such as inference and learning)

[Source: GB/T 5271.28-2001, 28.01.02]

3.1.2
artificial intelligence medical device; AIMD
medical device that uses AI technology to realize their intended use

Note 1: For example, independent software that uses machine learning, pattern recognition, rule inference and other technologies to realize its medical use.

Note 2: Medical devices that use embedded AI algorithm and AI chip to realize their medical use.

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